4/7/99

510(k) Summary

Ultramind International Ltd.

SmartVent™ 201 Portable Ventilator

510(k) Number K 981668

Submitter's Name:

A.M.E. Ltd.
14 Raul Wallenberg St.
Ramat Hachayal,
Tel-Aviv 69719, Israel

Contact Person:

Shoshana Friedman
117 Ahuzah St.
Ra'ananna 43373, Israel
Tel: 972-9-771-8130
Fax: 972-9-771-8131

Trade Name:

SmartVent™ 201 Portable Ventilator (Temporary name)

Classification Name:

Continuous Ventilator

Classification:

The FDA has classified these devices as a class II device (product code 73 CBK) and are reviewed by the Anesthesiology, Respiratory, and Defibrillator Devices Group.

Predicate Devices:

The ***SmartVent™ 201 Portable Ventilator*** is substantially equivalent to:

- TBIRD VS & AVS Ventilators (Bird Product Co.), cleared under K950484
- Oxylog 2000 (Dräger, Inc.), cleared under K943531.

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the ***SmartVent™ 201 Portable Ventilator*** complies with the following voluntary standards: ASTM F1100-90, ASTM F1246-91, MIL-STD-810E, ISO 10651-1, ISO 10651-2, ISO 10651-3, EN 60601-1-1, EN 60601-1-2.

Indication for Use:

The ***SmartVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The ***SmartVent™ 201*** ventilator is suitable for inter-hospital use, home and alternate-site use, transport and emergency use.

The ***SmartVent™ 201*** ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

Device Description:

The ***SmartVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is designed to treat a variety of clinical conditions. It can deliver oxygen-enriched air and may be used to administer nebulized medications by inhalation. The

SmartVent™ 201 can use external AC or DC power supply and contains an internal battery. Its operation is controlled by the ***SmartVent™ 201 Software.***

Substantial Equivalence:

Based on a series of safety and performance testing including a comparative study and analysis of similarities and differences we believe that the ***SmartVent™ 201*** is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 1999

Ms. Shoshana Friedman
Versamed Ltd.
14 Raoul Wallenberg Street
Ramat-Hachayal
Tel-Aviv 69719
ISRAEL

Re: K981668
SmartVent™ 201 Portable Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: January 10, 1999
Received: January 14, 1999

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulation.

On August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

INDICATIONS FOR USE

510(k) Number (if known): K981608

Device Name: ***SmartVent™ 201 Portable Ventilator***

Indications for Use:

The ***SmartVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ruth A. Carhart

(Division Sign-off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K981608

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)